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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,275	07/02/2007	Aki Honda	0760-0356PUS1	2612
2292 7590 08/09/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER SRIVASTAVA, KAILASH C				
ART UNIT		PAPER NUMBER		
1657				
NOTIFICATION DATE		DELIVERY MODE		
08/09/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/583,275

Applicant(s)

HONDA ET AL.

Examiner

Kailash C. Srivastava

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-5 and 7-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI.08)
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date: 20100802A
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

Informal Matters

1. Note that the correct Serial Number for instant Application currently under prosecution at the United States Patent and Trademark Office (i.e., USPTO) is 10/583,275. Please ensure that the correct U.S. Serial Number (i.e., 10/583,275) for the instant application is cited in all future correspondence with this Office.
2. The assigned Art Unit location for the instant application (i.e., 10/583,275) at the USPTO is 1657. To aid in correlating any papers for this application, all further correspondence regarding this application (i.e., 10/583,275) should be directed to Art Unit 1657.
3. The assigned Examiner to the instant application (i.e., 10/583,275) at the USPTO is Kailash C. Srivastava. To aid in correlating any papers for this application, all further correspondence regarding this application (i.e., 10/583,275) should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.

Claims Status

4. According to the Amended Claims set filed 02 July 2007, the current Claims status is as follows:

- ☒ Claim 6 has been cancelled;
- ☒ Claims 1, 9, 11, 13, and 16 have currently been amended; and
- ☒ Claims 1-5 and 7-2 are currently pending.

5. Please note the following irregularities with the currently presented Claims:

Claims do not comply with 37 C.F.R. §1.121 (See M.P.E.P. §714 [R-5] (c)) because of following reasons:

- A. In the claim listing, the status of **every** claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

Please note, Status of currently presented Claims 2-5, 7-8, 10, 12, 14-15 and 17-26 has not been indicated according to the requirements in M.P.E.P. §714 [R-5](c)(2) as described *supra*.

- B. The text in the amended claims has not been indicated in accordance with M.P.E.P. §714 [R-5](c)(2) which states as follows:

All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn — currently amended."

In instantly amended Claims 1, 9, 11, 13 and 16 additions and deletions have not been indicated according to M.P.E.P. §714 [R-5](c)(2) as described *supra*. Several original claims have not been so indicated with an identifier.

- C. Applicant is advised that Claims 3-5, 7-8, 18-20 and 23-26 will be objected to because of the following informalities:

- ♦ Claims 3-5, 18-20 and 23-36 are multiple dependent Claims; and
- ♦ Claims 7-8 will be objected to under 37 CFR §1.75(c), as being of improper dependent form because Claims 7-8 depend from a cancelled claim 6. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

6. During a telephone interview on 02 August 2010 (please see attached interview summary), Applicants' Representative clarified to the Examiner that Claims 7-8 depend from Claim 1, not from the cancelled Claim 6. Accordingly, in the following restriction requirement, Claims 7-8 are grouped with Group I invention. Please amend the Claim set to reflect this correction in response to the instant Office Action.

Examiner is issuing the following Office Action to expedite the prosecution in the instant application. Appropriate correction, as indicated *supra*, however, is suggested in response to the instant Office Action.

Election /Restriction

7. This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1 and 37 C.F.R.

§1.475. Restriction to one of the following inventions is required under 35 U.S.C. §121 and §372.

In accordance with PCT rules cited *supra*, applicant is required, in reply to the instant Office Action, to select a single invention to which the claims must be restricted.

- Group I, consisting of claims 1-5, 7-8 and 18-20 drawn to a method to measure an environmental biological allergen by measuring protease activity of said allergen;
- Group II consisting of Claims 9-12 and 21-23 drawn to an instrument to measure an environmental biological allergen by measuring protease activity of said allergen on a porous support; and
- Group III, consisting of claims 13-17 and 24-26, drawn to an apparatus to measure environmental biological allergen, wherein said apparatus comprises a vessel to contain the protease substrate and an optical measuring device to measure fluorescence or the change in absorbance in the vessel.

Inventions are Independent or Distinct

8. The inventions listed in Groups I-III *supra* do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The patent rules under 37 C.F.R. §1.475 for Unity of Invention (Paragraphs (a), (b) and (c)) are cited below:

§1.475 Unity of Invention before the International Searching Authority, the International Preliminary Examining Authority and during the National Stage

- (a) An International and National Stage Application shall relate to one invention only, or to a group of inventions so linked as to form a general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical

relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as whole, makes over the prior art.

(b) An International or a National stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

Inventions described in Groups I-III *supra* fall within category (2), method and products because the instrument/apparatus or device are comprised of a number of components and accordingly are construed as compositions.

9. PCT Rule 13.2 does not provide for multiple compositions, or multiple methods of making a composition, or multiple methods of use of a composition within a single application. Thus, the first appearing composition is combined with a corresponding first method of making said composition (if applicable) and/ or use of said composition. However, the additional composition and method claims each constitute a separate inventive Group.

In addition to the requirement that a Group of inventions must belong to one of the specific categories provided by PCT Rule 13.2, the inventions in the category, e.g., as a composition and a method of use of said composition, must have a special technical feature that unites them. See Patent rules under 37 C.F.R. §1.475, where a special technical feature is a contribution OVER THE PRIOR ART.

The special technical feature of the group I method is to measure an environmental biological allergen by measuring the protease activity of said allergen. Said method is well known in the relevant art for e.g., Pirzad (GB2 351 560 A, Item BA, Applicants' IDS filed

03/14/2008) teaches a method to identify allergen by measuring protease activity with a colorimetric amine reagent (See for e.g., Abstract, Lines 5-10 and e.g., Page 4, Lines 2-27 to Page 10, Line 6; Figures 2-4). Gough et al (1999. The Cysteine Protease Activity of the Major Dust Mite Allergen Der p 1 Selectively Enhances the Immunoglobulin E Antibody Response. Journal of Experimental Medicine, Volume 190, Number 12, December 20, 1999, Pages 1897-1901), also teach the protease activity of the mite allergen and a method to measure it.

The special technical feature of Groups II-III apparatus/ instrument is to allow the measurement of said allergens by measuring protease activity of said allergen, wherein fluorescence or change in absorbance is measured and said instrument/apparatus comprises a vessel to contain the protease substrate. This aspect is also taught in the prior art, e.g., Pirzad (GB2 351 560 A). Pirzad teaches e.g., an apparatus having at least one vessel (See Page 10, Line 7 to Page 11, Line 14 and Figure 1).

Thus as illustrated *supra*, the special technical features of inventive Groups I- III are well documented in the pertinent prior art. Consequently, the inventions instantly presented in Groups I-III do not make a contribution over the prior art and hence no special technical features exist among the inventions of Groups I-III.

Since no special technical feature exists among each of the inventions in Groups I-III, and because the special technical features of each of Group I-III inventions is not a contribution over the prior art, there is no unity of invention.

10. In accordance with 37 C.F.R. §1.499, applicant (S) is/are required, in response to this action, to elect a single invention to which the claims must be restricted.

Applicant(s) is/are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 C.F.R. §1.143).

11. Applicant (s) is/are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. §1.48(b) and by the fee required under 37 C.F.R. §1.17(i).

12. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. § 1.116; amendments submitted after allowance are governed by 37 C.F.R. § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §101, §102, §103, and §112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. §121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. §804.01.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:00 A.M. to 5:30 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on (571)-272-0925 Monday through Thursday 7:30 A.M.

to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

/Kailash C Srivastava/
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